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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,345	09/16/2003	Levon Arakelyan	Q71975	2068

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EXAMINER
CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,345	ARAKELYAN ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11, 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 19 July 2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-17 are currently pending. Claims 10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 20 April 2006. Claims 1-9, 11, and 13-17 are examined herein.

Specification

The substitute Specification has been accepted.

Claim Objections

Claims 1, 15 and 17 are objected to for the following informalities: Claim 1 recites, in numerous places, "performing phase II (or phase III or IV) clinical trial". This is grammatically

incorrect and should read, "performing phase II clinical trials or performing a phase II clinical trial". Correction is requested.

Claims 15 and 17 recite, "related studies, the comprising". A word is missing and perhaps Applicant intended the claim to read "related studies, the method comprising". Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "performing a pre-clinical phase in which a computer model for pharmacokinetics and pharmacodynamics of the drug is created and adjusted based on in vitro studies and in vivo studies". It is unclear as to what about the in vitro or in vivo studies is utilized in order to create or adjust a model. There are no parameters set forth in the claim such that this is clear. Clarification is requested.

Claim 1 recites, "wherein the phase I clinical trial comprises a plurality of sub-steps". It is unclear as to what those sub-steps are intended to be and where they fit into the trial". Clarification is requested.

Claim 1 recites, "determining maximal tolerated dose, minimum effective dose…in conjunction with the computer simulations". It is unclear as to what about the computer simulations the dose is in conjunction with. Clarification is requested.

Claim 1, analyzing interim results of step h, to choose the most promising regimens…". It is unclear as to what the interim results are. There are no interim tests in step h. Further, what constitutes the "most" promising? Clarification is requested.

Claim 2 recites, "phase I sub-step clinical trial results". There is insufficient antecedent basis in the claim for "sub-set results". Clarification is requested.

Claim 17 recites, "developing a strategy for a next sub-step in phase I clinical trial". There is insufficient antecedent basis in the claim for a next sub-step, as a first sub-step was not performed. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Iliadis et al. (Computers and Biomedical research (2000) Vol. 33, pages 211-226; PTO 1449 Reference 30). The rejection is re-iterated below.

The instant claims are drawn to a method for performing clinical trials for a new drug for cancer related studies comprising performing pre-clinical phase in which a computer model for

pk/pd is created; a method for performing clinical trials for a new drug comprising performing phase I clinical trial wherein dose-escalation trial is performed with computer simulation; and a method of performing clinical trials for a new drug comprising developing a strategy for a next sub-step in phase I in conjunction with computer predictions.

Iliadis et al. teach a method in which optimization of cancer treatment is determined by using a mathematical model of pharmacokinetics of anticancer drugs, antitumor efficacy, and drug toxicity (abstract). The first approach relies on modeling to simulate the fate of drug concentration, tumor size, and WBC count (page 218, paragraph 5) (claim 15). The second phase involves protocol implementation, based upon the model (page 218, paragraph 7) (claim 16). The protocols are used clinically, as outlined on page 219. Lastly, optimization of the protocols is performed (page 219, paragraph 5) (claim 17).

Response to Arguments

Applicant argues that Iliadis et al. conducted no clinical trial and therefore the reference is not applicable. Applicant goes on to summarize the Iliadis et al. reference.

This is not persuasive, as Applicants invention is drawn to performing computer simulations based on clinical trial data. Iliadis fairly reads on models based upon computer simulations and data gathered from clinical trials.

Conclusion

No claims are allowed.

The outstanding rejections under 35 USC 112, 1st paragraph have been withdrawn in view of the amendments to the claims adding "for cancer related studies".

Inquiries

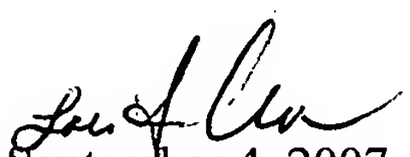
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.



September 4, 2007
Lori A. Clow, Ph.D.
Primary Patent Examiner
Art Unit 1631